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| 09/699,136      | 10/27/2000  | Daniel Santi         | 300622004900        | 6454             |

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EXAMINER

KERR, KATHLEEN M

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1652

DATE MAILED: 07/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/699,136

Applicant(s)

SANTI ET AL.

Examiner

Kathleen M Kerr

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 17, 24 and 26-40 is/are pending in the application.
- 4a) Of the above claim(s) 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 17, 24 and 26-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 1652

## **DETAILED ACTION**

### ***Application Status***

1. In response to the previous Office action (Paper No. 8 mailed February 14, 2002), Applicants filed an amendment and response (Paper No. 10). Said amendment cancelled Claims 2-16, 18-23, and 23, amended Claims 1, 17, and 24, and added new Claims 26-40. Thus, Claims 1, 17, 24, and 26-40 are pending in the instant application.

### ***Restriction***

2. Newly submitted Claim 40 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claim 40 is related to the originally presented invention, as found presently in Claims 1, 17, 24, and 26-39, is related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the host cell can be used for a materially different process of using that product, such as in production of a recombinant, purified polyketide synthase enzyme. Thus, Claim 40 is patently distinct.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 40 is withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03.

Art Unit: 1652

This application contains Claim 40 drawn to an invention non-elected by original presentation as noted above. A complete reply to the final rejection must include cancellation of non-elected claim or other appropriate action (37 C.F.R. § 1.144) See M.P.E.P. § 821.01.

Claims 1, 17, 24, and 26-40 are pending in the instant application. Claim 40 is withdrawn from further consideration as a non-elected invention. Thus, Claims 1, 17, 24 and 26-39 will be examined herein.

***Priority***

3. The instant application is granted the benefit of priority for the U.S. Provisional Application No. 60/161,703 filed on October 27, 1999 as requested in the newly filed declaration (Paper No. 12).

***Information Disclosure Statement***

4. The information disclosure statement (IDS) filed on August 15, 2001 (Paper No. 9) has been reviewed, and its reference has been considered as shown by the Examiner's initials next to each citation on the attached copy. The Examiner notes that this IDS was previously overlooked in the record since it had been filed prior to a first Office action on the merits.

***Declaration***

5. A substitute declaration was filed on June 12, 2002 (Paper No. 12) and has been entered. This declaration replaces the previous declaration to correct the priority claim.

Art Unit: 1652

***Drawings***

6. As previously noted, the drawing has been approved by the Draftsmen and are, therefore, entered as formal drawings acceptable for publication upon the identification of allowable subject matter.

***Compliance with the Sequence Rules***

7. By virtue of Applicant's amendment to the specification and supply of a computer readable form of the sequence listing, the instant specification now is in full compliance with the sequence rules.

***Withdrawn - Objections to the Specification***

8. Previous objection to the Abstract for not completely describing the disclosed subject matter is withdrawn by virtue of Applicant's amendment to the Abstract.

***Maintained - Objections to the Specification***

9. Previous objection to the specification for containing incorrect priority data in the first lines of the specification is maintained. Priority to 60/161,414 and 60/206,082 is not requested in the new declaration and must be removed from the first lines of the specification. Appropriate correction is required.

10. Previous objection to the specification for containing figures and/or graphs embedded within the text is withdrawn by virtue of Applicants' amendment to the specification deleting the figures within the text. However, Applicants have amended the specification to include new Figures 2-9 (see amendments to the Brief Description of the Drawings on page 6 of the instant

Art Unit: 1652

specification); no such figures have been filed. Thus, the figures originally embedded on pages 58, 59, 62 (color), 74, 82, 83, 84, and 87 must be filed along with original Figure 1 as a complete set of amended drawings for review by the Draftsman.

Appropriate correction to the specification is required.

***Withdrawn - Objections to the Claims***

11. Previous objection to Claim 8 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn by virtue of Applicants' cancellation of said claim.

12. Previous objection to Claims 14, 19, and 20 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn by virtue of Applicants' cancellation of said claims.

***Withdrawn - Claim Rejections - 35 U.S.C. § 112***

13. Previous rejection of Claims 1-5 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "precursor required for biosynthesis of the product" is withdrawn by virtue of Applicants' cancellation or amendment of said claims.

14. Previous rejection of Claims 2-25 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "substantially" is withdrawn by virtue of Applicants' cancellation or amendment of said claims.

Art Unit: 1652

15. Previous rejection of Claim 3 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "primary metabolite" is withdrawn by virtue of Applicants' cancellation of said claim.

16. Previous rejection of Claims 5-11 under 35 U.S.C. § 112, second paragraph, as being indefinite for the confusing combination of "modular, iterative, or fungal" is withdrawn by virtue of Applicants' cancellation of said claims.

17. Previous rejection of Claims 5-25 under 35 U.S.C. § 112, second paragraph, as being indefinite for the abbreviation "PKS" is withdrawn by virtue of Applicants' cancellation of said claims and amendment to the remaining claims.

18. Previous rejection of Claims 14-17, 19, and 20 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "derived from" is withdrawn by virtue of Applicants' amendment and/or cancellation of said claims.

19. Previous rejection of Claims 15 and 16 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "modified to overexpress" is withdrawn by virtue of Applicants' cancellation of said claims.

20. Previous rejection of Claim 23 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "**the** *birA* gene" (emphasis added) is withdrawn by virtue of Applicants' cancellation of said claim.

Art Unit: 1652

21. Previous rejection of Claims 1-25 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicants' amendment and/or cancellation of said claims. The amended claims also have written description defects that are addressed below in a new written description rejection.

22. Previous rejection of Claims 1-25 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicants' amendment and/or cancellation of said claims.

***Withdrawn - Claim Rejections - 35 U.S.C. § 102***

23. Previous rejection of Claims 1-2 and 4-5 under 35 U.S.C. § 102(b) as being anticipated by Kealey *et al.* is withdrawn by virtue of Applicants' amendment and/or cancellation of said claims.

24. Previous rejection of Claims 2-3 under 35 U.S.C. § 102(b) as being anticipated by Tuchman *et al.* is withdrawn by virtue of Applicants' cancellation of said claims.

***Withdrawn - Claim Rejections - 35 U.S.C. § 103***

25. Previous rejection of Claims 1-2 and 4-6 under 35 U.S.C. § 103(a) as being unpatentable over Stassi *et al.* in view of Kao *et al.* is withdrawn by virtue of Applicants' amendment and/or cancellation of said claims.

26. Previous rejection of Claims 7-8 under 35 U.S.C. § 103(a) as being unpatentable over Stassi *et al.* and Birch *et al.* in view of Kao *et al.* is withdrawn by virtue of Applicants' amendment and/or cancellation of said claims.

Art Unit: 1652

27. Previous rejection of Claims 1-2 and 4-13 under 35 U.S.C. § 103(a) as being unpatentable over Stassi *et al.* and Birch *et al.* in view of Barr *et al.* is withdrawn by virtue of Applicant's amendment and/or cancellation of said claims.

28. Previous rejection of Claims 14-17 under 35 U.S.C. § 103(a) as being unpatentable over Stassi *et al.* and Birch *et al.* in view of Barr *et al.* and in further view of McKie *et al.* is withdrawn by virtue of Applicant's amendment and/or cancellation of said claims.

29. Previous rejection of Claims 18 and 24-25 under 35 U.S.C. § 103(a) as being unpatentable over Stassi *et al.* and Birch *et al.* in view of Donadio *et al.* and in view of Barr *et al.* is withdrawn by virtue of Applicants' cancellation and/or amendment of said claims.

30. Previous rejection of Claim 21 under 35 U.S.C. § 103(a) as being unpatentable over Stassi *et al.* and Donadio *et al.* in view of Barr *et al.* is withdrawn by virtue of Applicants' cancellation of said claims.

## **NEW OBJECTIONS/REJECTIONS**

### ***Objections to the Specification***

31. The specification is objected to for references to locations of graphs and figures throughout the specification, which graphs and figures have been removed from the text of the specification and amended as drawings (or that is Applicants' intent). See for example, page 56, line 9 and page 61, line 7. All such references must be corrected.

Art Unit: 1652

32. The amendment filed May 14, 2002 (Paper No. 10) is objected to under 35 U.S.C. § 132 because it introduces new matter into the disclosure. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure, is as follows: in Claims 30, 34, and 38, "from a gene of an *E. coli* phage". Applicants note the support can be found in Example 1. Example 1 is lengthy (pages 51-71), and the Examiner cannot locate clear support.

Applicant is required to cancel the new matter in the reply to this Office Action or to particularly point to (page and line number) the support in the specification as originally filed.

#### ***Claim Objections***

33. Claims 30, 34, and 38 are objected to for containing new matter, as noted above.

Applicant is required to cancel the new matter in the reply to this Office Action or to particularly point to (page and line number) the support in the specification as originally filed.

34. Claims 30, 34, and 38 are objected to for a typographical error. The period after the second appearance of "*E. coli*" in the second line of each claim is misplaced. Appropriate correction is required.

#### ***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

35. Claims 1, 17, and 26-35 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

Art Unit: 1652

applicant regards as the invention. In Claim 1, the phrase "for biosynthesis of a polyketide produced by a modular polyketide synthase (PKS) produced by a PKS gene or genes in said host cell" is unclear. The instant claims are drawn to *E. coli* host cells that do not natively contain PKS genes. Thus, it seems that for this biosynthesis to be clear, an additional limitation on the host cells is that they must comprise vectors comprising PKS genes or they must comprise recombinant PKS genes incorporated into the genome. Without such a limitation, the above phrase is unclear. Appropriate clarification is required.

36. Claims 24 and 36-39 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "wherein said genes produce enzymes capable of making S-methylmalonyl CoA, and a modular polyketide synthase (PKS) gene" is wholly unclear. The lack of appropriate indentation renders the claim unclear since the epimerase gene would seem to produce enzymes capable of (1) making S-mm-CoA and (2) a PKS gene. Appropriate correction is required.

37. Claims 28, 29, 32, 33, 36, and 37 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how said mm-CoA mutase gene (singular) can be two genes – mutA and mutB. While it is evident from the specification that these are subunits of a protein, both of which are required for activity, this discrepancy between singular and plural renders the claims unclear. Appropriate correction is required.

Art Unit: 1652

38. Claims 28, 29, 32, 33, 36, and 37 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase “**the** *Propionibacterium shermanii* methylmalonyl CoA mutase gene” and “**the** *Streptomyces cinnamonesis* methylmalonyl CoA mutase gene” (emphasis added) indicates a single, particular sequence. The specification described sequences in Marsh *et al.* and Birch *et al.*, respectively, for these genes in these species. It is unclear if it is these exact sequences from Marsh *et al.* and Birch *et al.* are limitations or if any sequence from *Propionibacterium shermanii* or *Streptomyces cinnamonesis* is appropriate to the limitation. Appropriate clarification is required.

39. Claims 30, 34, and 38 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase “from a gene of an *E. coli* phage” is unclear. If this phrase limits to only endogenous phage from *E. coli*, then the previous phrase “an *E. coli* gene” would encompass such a term. If this phrase limits to any promoter found in an *E. coli* phage, which could be recombinant, there is no tangible limitation since any promoter can be transferred into an *E. coli* phage. Thus, the metes and bounds of the phrase are unclear. Appropriate clarification is required.

40. Claims 31, 35, and 39 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase “PKS gene is a gene that encodes a 6-dEB synthase protein” is unclear. The DEBS PKS consists of at least three genes encoding at least 3

Art Unit: 1652

large proteins. The parent claims require polyketide production, which would require all three proteins. However, the limitation in the instant claims is singular, a protein. Thus, the instant claims are confusing. Appropriate clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

41. Claims 1, 17, 24, and 26-39 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner notes that Claims 28, 29, 32, 33, 36, and 37 are included in the instant rejection based on the lack of clarity of the instant claims as noted above. Claims 1 and 24 are drawn to *E. coli* bacteria that express any *P. shermanii* or an *S. cinnamonensis* methylmalonyl CoA mutase gene that is claimed solely by function and without any structural limitations. Claims 1 and 24 also require that the *E. coli* bacteria express any *P. shermanii* epimerase gene that is claimed solely by function and without any structural limitations.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and*

Art Unit: 1652

Co., 1997 U.S. App. LEXIS 18221, at \*23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

In the instant specification, a *P. shermanii* gene encoding methylmalonyl CoA mutase is described according to Marsh *et al.*, and a *S. cinnamonensis* genes encoding methylmalonyl CoA mutase is described according to Birch *et al.* (see page 15). Having only a single gene from each species, one of skill in the art would be unable to predict the structure of any other members of the claimed genus. In the instant specification, a *P. shermanii* gene encoding an epimerase is described according to Leadlay *et al.* (see page 18). Having only a single gene, one of skill in the art would be unable to predict the structure of any other members of the claimed genus. Therefore, claims drawn to bacteria containing the genus of said genes are also not adequately described.

42. Claims 30, 34, and 38 are rejected under 35 U.S.C. § 112, first paragraph, new matter, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims contain new

Art Unit: 1652

matter. The added material, which is not supported by the original disclosure, is "from a gene of an *E. coli* phage".

Applicant is required to cancel the new matter in the reply to this Office Action or to particularly point to (page and line number) the support in the specification as originally filed.

### ***Summary of Pending Issues***

43. The following is a summary of the issues pending in the instant application:

- a) Claim 40 is directed to a non-elected invention.
- b) The specification stands objected to for containing incorrect priority data.
- c) The specification stands objected to for references to Figures 2-9, which are absent.
- d) The specification stands objected to for references to locations of graphs and figures.
- e) The amendment filed May 14, 2002 (Paper No. 10) stands objected to under 35 U.S.C. § 132 because it introduces new matter into the disclosure.
- f) Claims 30, 34, and 38 stand objected to for containing new matter.
- g) Claims 30, 34, and 38 stand objected to for a typographical error.
- h) Claims 1, 17, and 26-35 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the unclear phrase "for biosynthesis of a polyketide produced by a modular polyketide synthase (PKS) produced by a PKS gene or genes in said host cell".
- i) Claims 24 and 36-39 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the unclear phrase "wherein said genes produce enzymes capable of making S-methylmalonyl CoA, and a modular polyketide synthase (PKS) gene".
- j) Claims 28, 29, 32, 33, 36, and 37 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for singular vs. plural gene terms.
- k) Claims 28, 29, 32, 33, 36, and 37 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the confusing phrase "**the** *Propioinibacterium shermanii* methylmalonyl CoA mutase gene" and "**the** *Streptomyces cinnamonesis* methylmalonyl CoA mutase gene" (emphasis added) indicating a single, particular sequence.
- l) Claims 30, 34, and 38 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the unclear phrase "from a gene of an *E. coli* phage".
- m) Claims 31, 35, and 39 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the unclear phrase "PKS gene is a gene that encodes a 6-dEB synthase protein".
- n) Claims 1, 17, 24, and 26-39 stand rejected under 35 U.S.C. § 112, first paragraph, written description.
- o) Claims 30, 34, and 38 stand rejected under 35 U.S.C. § 112, first paragraph, new matter.

Art Unit: 1652

*Conclusion*

44. Claims 1, 17, 24, and 26-39 are rejected. Claim 40 is withdrawn from consideration.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 305-3014 for After Final communications.

Application/Control Number: 09/699,136

Page 16

Art Unit: 1652

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to be 'Acl' or similar, located in the center of the page.

KMK  
July 24, 2002